

K082305

**G2 EXPRESS™ Filter System – Femoral and Jugular/Subclavian Delivery Kits
510(k) Summary
21 CFR 807.92**

As required by the Safe Medical Devices Act of 1990, coded under Section 513, Part (I)(3)(A) of the Food, Drug and Cosmetic Act, a summary of the information upon which substantial equivalence determination is based as follows:

1. Submitter Information:

Applicant: Bard Peripheral Vascular, Inc
1625 West 3rd Street
PO Box 1740
Tempe, Arizona 85280

Phone: 480-303-2524

Fax: 480-449-2546

Contact: Genevieve Balutowski
Associate Project Manager, Regulatory Affairs

OCT 31 2008

2. Subject Device:

Device Trade Name: **G2 EXPRESS™ Filter System – Femoral Delivery Kit
and G2 EXPRESS™ Filter System –
Jugular/Subclavian Delivery Kit**

Common or Usual Name: Filter, Intravascular, Cardiovascular

Classification: Class II

Classification Panel: Cardiovascular

3. Predicate Device:

G2 EXPRESS™ Filter System – Femoral Delivery Kit (K080668)

G2 EXPRESS™ Filter System – Jugular/Subclavian Delivery Kit (K080668)

4. Summary of Change:

The modification from the predicate device, the G2 EXPRESS™ Filter System – Femoral and Jugular/Subclavian Delivery System, to the subject device, the G2 EXPRESS™ Filter System Femoral and Jugular/Subclavian Delivery System, consisted of design improvements of the femoral and jugular/subclavian delivery kits.

5. Device Description:

The G2 EXPRESS™ Filter consists of 12 shape-memory nitinol wires emanating from a central nitinol sleeve with a snare tip. These 12 wires form two levels of emboli filtration: the legs provide the lower level of filtration and the arms provide the upper level of filtration. The G2 EXPRESS™ Filter is intended to be used in the inferior vena cava with diameters less than or equal to 28 mm.

The G2 EXPRESS™ Filter System – Jugular/Subclavian Delivery Kit consists of a 10 Fr I.D. introducer sheath and dilator set and a delivery device preloaded with the G2 EXPRESS™ Filter. The introducer sheath and dilator are used to gain access to the inferior vena cava via a jugular approach. The delivery device fits within the introducer sheath and consists of a delivery mechanism to deploy the G2 EXPRESS™ Filter.

The G2® EXPRESS™ Filter System – Femoral Delivery Kit consists of a 7 Fr I.D. introducer catheter and dilator set and a storage tube preloaded with the G2 EXPRESS™ Filter and delivery device. The introducer sheath and dilator are used to gain access to the inferior vena cava via a femoral approach. The delivery device fits within the introducer sheath and consists of a delivery mechanism to deploy the G2 EXPRESS™ Filter.

6. Indication for Use of Device:

The G2 EXPRESS™ Filter System – Femoral and Jugular/Subclavian Delivery Kits are indicated for use in the prevention of recurrent pulmonary embolism via permanent placement in the vena cava in the following situations:

- Pulmonary thromboembolism when anticoagulants are contraindicated.
- Failure of anticoagulant therapy for thromboembolic disease.

- Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced.
- Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated.
- G2 EXPRESS™ Filter may be removed according to the instructions supplied under the section labeled: Optional Procedure for Filter Removal.

7. Technological Comparison to Predicate Device:

The technological characteristics of the subject device, the G2 EXPRESS™ Filter System – Femoral and Jugular/Subclavian Delivery Kits, are substantially equivalent to those of the predicate devices, the G2 EXPRESS™ Filter System – Femoral and Jugular/Subclavian Delivery Kits (K080668), in terms of intended use, indications for use, application, user population, basic design, fundamental scientific technology, performance, and sterilization method.

8. Conclusions:

The G2 EXPRESS™ Filter System – Femoral and Jugular/Subclavian Delivery Kits met all predetermined acceptance criteria of design verification and validation as specified by applicable standards, guidance, test protocols and/or customer inputs. The G2 EXPRESS™ Filter System – Femoral and Jugular/Subclavian Delivery Kits is substantially equivalent to the legally marketed predicate device, the G2 EXPRESS™ Filter System – Femoral and Jugular/Subclavian Delivery Kits.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 31 2008

Bard Peripheral Vascular, Inc.
Ms. Genevieve Balutowski
Senior Regulatory Affairs Specialist
P.O. Box 1740
Tempe, AZ 85280

Re: K082305

Trade/Device Name: G2 Express Filter System – Femoral and Jugular/Subclavian Delivery Kits
Regulation Number: 21 CFR 870.3375
Regulation Name: Cardiovascular Intravascular Filter
Regulatory Class: Class II (two)
Product Code: DTK
Dated: September 29, 2008
Received: September 30, 2008

Dear Ms. Balutowski:

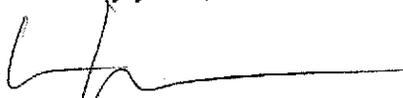
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Bran D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: G2 EXPRESS™ Filter System – Femoral and Jugular/Subclavian Delivery Kits

Indications for Use:

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- G2 EXPRESS™ Filter may be removed according to the instructions supplied under the section labeled: Optional Procedure for Filter Removal.

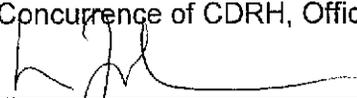
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K042205

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